PATENT

Docket No.: 9425/46702

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS	:	Samuel BOGOCH
SERIAL NO.	:	(Continuation of 08/031,562)
FILED	:	Herewith
FOR	:	RECOGNIN VACCINES
GROUP ART UNIT	:	1813 (Anticipated)
EXAMINER	:	Unassigned

ASSISTANT COMMISSIONER
FOR PATENTS
Washington, D.C. 20231

PRELIMINARY AMENDMENT

SIR:

Prior to examination of the above-identified application, please make the amendments noted below.

IN THE TITLE

Change the title to read: --METHODS AND COMPOSITIONS FOR STIMULATING THE IMMUNE SYSTEM--.

IN THE SPECIFICATION

After the title, insert the following paragraph:

--This application is a continuation of application Serial No. 08/031,562, filed March 16, 1993, the entire disclosure of which is incorporated by reference.--

Page 7, before line 19: Insert the following:

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1

This figure is divided into 12 sections, labelled "a" through "l". Sections "a" through "i" of this figure demonstrate the specificity of the attachment to (and when combined with a histological stain, the specificity of staining of) malignant cells of various cell types by anti-Recognin antibody. Sections "j", "k" and "l" demonstrate that anti-Recognin antibody is cytotoxic to malignant cells. (see full description under Example 1).

Figure 2

This figure quantitates the inhibition of malignant cell growth and/or cytotoxicity to malignant cells by anti-Recognin antibody. By serial dilution of the antibody it is determined that the antibody is cytotoxic to malignant cell growth in concentrations of picograms per cell. (see full description under Example 6).

Figure 3

This figure demonstrates three things: 1) in healthy individual humans without tumors, the concentration of anti-Recognin antibody increases with age as the risk of clinical cancer increases; 2) the concentration of anti-Recognin antibody increases markedly in individuals with proven human breast cancer; and 3) the concentration of anti-Recognin antibody returns to normal concentrations after successful treatment of human breast cancer. (see full description under Example 7).

REMARKS

The claims in the parent application have been replaced with new claims 1 through 13 Accordingly, claims 1 through 13 are presented for examination on the merits.

Support for new claims 1 through 13 is found throughout the specification. In particular, claims 1 through 4 are supported by the disclosure set forth in Example 8 at pages 17 through 18 of the specification. It is disclosed in Example 8 that a composition containing malignin, recognin L, recognin M or a fragment thereof having the same immunological specificity is administered to a subject and that as a consequence, the level of anti-recognin antibody and immune cells in the subject is raised. It is also disclosed that the first dosage may be followed by a second and third dosage, a typical dosage amount being approximately 1 mg.

Claims 5 and 6 are directed to an aspect of the invention which provides a composition for stimulating the immune system of a subject to produce and release antimalignin antibody. The composition contains malignin, recognin L, recognin M or a fragment thereof having the same immunological specificity (claim 5). This claim is supported by the disclosure at pages 17 through 18 (Example 8). Claim 6 is supported by original claim 4.

Claims 7 through 11 are directed to an aspect of the invention which provides a device for removing cancer cells from the body. These claims are supported by the disclosure at page 19 (Example 11).

Claim 12 is directed to a process for quantitatively detecting antimalignin antibody and immune cells having specificity for malignin, recognin L and/or recognin M and correlating the amounts of such cells to the presence of cells transformed to the malignant state. This claim is supported by the disclosure of Figure 3, Examples 2, 3 and Example 8.

Claim 13 is directed to an antimalignin antibody having a cytotoxic agent attached thereto. Claim 13 is supported by original claim 4.

It is respectfully submitted that the present claims are fully supported by the specification and contain no new matter. It is also submitted that the claims are enabled by the specification.

The Examiner is invited to contact the undersigned to discuss any matter concerning this application.

The Office is authorized to charge any fees or credit any overpayment under 37 C.F.R. § 1.16 or 1.17 to Deposit Account No. 11-0600.

Respectfully submitted,

KENYON & KENYON

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